

Claims 44-124, 130-139, 146-200, 213-330 have been canceled. Claims 1-43, 125-129, 140-145, 201-212 and newly presented claims 331-336 are still at issue and are present for examination.

Applicants' arguments filed on 3/6/08, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Upon further view of elected invention the species election directed to claims 5, 10, 16, 39, 42 is hereby withdrawn.

Claim Objections

Claims 207-208 are objected to because of the following informalities: The term "Magnasweet^R 100" in claims 207-208 appear to refer to trademark name(s). Applicant is advised to substitute said term with the generic compound(s) associated with said trademark name(s). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-43, 125-129, 140-145, 201-212 and 331-336 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlgren (cited previously) in view of Khanapure et al. (U.S. Patent No. 6,706,714, issued 3/2004). In traversal of this rejection

applicant argues the following: **(1)** Ahlgren discloses microspheres containing certain fatty acids and discloses for example sumatriptan in a true laundry list of active agents that may be used in the disclosed invention. However, nowhere in the reference, or in the current drug formulation/preparation techniques is one of ordinary skill in the art is directed to, or enabled to make, the presently claimed rapid absorption pharmaceutical composition.

The examiner has failed to provide specific factual findings predicted on sound technical and scientific reasoning to support her conclusion of common knowledge. Applicant demands that the examiner produces authority for her statement in the form of documentary evidence and thereby show how one of ordinary skill would have found it obvious to go from Ahlgren to the present claimed invention.

(2) According to applicant present claim 1 requires a “rapid absorption” pharmaceutical composition comprising an effective amount of at least one 5-HT agonists, at least one spheronization aid and at least one solubility enhancer and as explained in paragraph [0017] of the specification having lower T_{50} with an equal or higher C_{max} of an oral dosage form when compared to currently marketed triptan product. This is no small feat, and to simply dismiss this important advancement as obvious over Ahlgren in view of current drug formulation techniques is incorrect and improper.

(3) The concept of “rapid absorption” formulation came from applicant’s own disclosure. IN view of applicant, while the KSR Court rejected a rigid application of the teaching, suggestion or motivation test in an obviousness inquiry, the Court

acknowledged the importance of identifying "a reason" that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does" in an obvious determination. This requirement applies to applicant's presently claimed composition.

Finally, applicant concludes that since the examiner fails to present prima facie case and because improper Official Notice has been taken, applicant's request the withdrawal of the rejection.

These arguments were fully considered but were found **unpersuasive**. In response to applicant's **first** argument, it is true that Ahlgren was cited in order to demonstrate that comestible pharmaceutical compositions comprising glyceryl palmitostearate, , fatty acid esters, Gelucire 50/13, sweeteners, flavorants etc. together with sumatriptan microspheres for treating migraine were known in the prior art. It is true that Ahlgren did not teach the instantly claimed "rapid absorption composition" word for word and it is for this reason that said art was cited as 103 and not 102 against instant claims. Besides, Ahlgren does not need to enable how to make the instant invention because, as stated previously, the state of prior art at the time of filing of this application, already enables making such composition.

However, in order to meet applicant's demand that the examiner provides an exemplary documentary evidence in support of her position, Khanapure is hereby brought up to applicant's attention. Khanapure teaches formulations comprising cyclooxygenase 2 (Cox-2) inhibitors optionally comprising 5-Ht agonists (see columns 44-45), including sumatriptan, rizatriptan etc. for treating diseases and disorders

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including headache and migraines. In column 52, Khanapure teaches about monoglycerides, vegetable oils (spheronization agents) and polyvinylpyrrolidone (solubility enhancers) as part of their parenteral compositions. Such compositions of Khanapure would inherently be "rapid absorption" compositions for any ingestible and comestible drug.

The examiner would like to emphasize that said art was merely cited as an example representing the state of pharmaceutical (parenteral, comestible) composition preparation techniques and knowledge at the time of filing of this application.

With respect to applicant's **second** argument the examiner fully appreciates that instant invention may have contributed over the prior art but by reading the definition provided in paragraph [0017] of the specification for "rapid absorption" composition it is unclear what constitutes "higher" or "lower" and such qualitative definition cannot be relied upon to characterize the "rapid absorption" compositions claimed. It is also noted that applicant's graphs and data do not represent any error margins (bars) or standard deviations. Therefore, it is believed that the combination of cited art above is meeting the limitation of "rapid absorption" as recited in the claims and it is further believed that the examiner's position in contrast to applicant's view, is both proper and correct.

With regards to applicant's **third** argument, it should be noted that when it comes to pharmaceutical compositions, specially parenteral compositions, "rapid drug absorption" is always one of the primary concerns and motivations of one of ordinary skill in the art. After, all "rapid drug absorption" logically results in rapid relief of pain, resulting is patient's well being and improvement of his/her quality of life. There is no

need for a explicit reason or teaching in the cited art in support of the instant obviousness rejection. The examiner believes that the instant case fully supports KSR Court decision rejecting the requirement of rigid teaching or motivation to combine the cited art, in view of common sense.

Therefore, in view of the response provided above, in addition to explanations previously provided, the rejection remains.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656
